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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,229	10/17/2003	Douglas N. Hess	P-11127.00	9463

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EXAMINER

FAULCON JR, LENWOOD

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,229	HESS ET AL.	
	Examiner	Art Unit	
	Lenwood Faulcon, Jr.	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Allowable Subject Matter

1. The indicated allowability of claims 6-8 and 19-22 is withdrawn in view of the newly discovered reference(s) to Grandjean (U.S. Patent No. 5,716,391), Peterfeso et al. (U.S. Patent No. 6,298,272), and Altman et al. (U.S. Patent No. 6,416,510), Keogh et al. (U.S. 2002/0138109). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

2. Claims 1-8, 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Min et al. (U.S. Patent No. 6,937,897) as applied in the previous Office Action of February 13, 2006, and further in view of Grandjean (U.S. Patent No. 5,716,391).

In regards to claim 1, as set forth in the previous Office Action of February 13, 2006, Min et al. discloses the claimed invention except for the helical fixation member being flexible; however, the Grandjean reference teaches that it is known to use a helical fixation member (41) that is flexible (see for example col. 4 lines 44-45). It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Min et al. to include a flexible helical fixation member as taught by Grandjean, since such a modification would provide the system with effective fixation and electrical contact with the desired tissue to be treated (see for example col. 4 lines 50-55).

In regards to claims 2-5, these claim are rejected for similar reasons as set forth in the previous Office Action of February 13, 2006.

In regards to claim 6, claim 6 present similar limitations as to claim 1 and is thus rejected for similar reasons.

In regards to claim 7, Examiner takes the position that the helical coil (41) as taught by Grandjean inherently has varying pitches, which would necessarily facilitate deflection of the coil.

In regards to claim 8, Examiner takes the position that helical fixation elements (12, 16) as taught by Min et al. are inherently preformed in order to conform to passageway of the lead in order for the helical fixation to reach the desired tissue site. Or in the alternative, Examiner takes the position that the Grandjean reference teaches of a flexible helical fixation element (41) which Examiner interprets to be preformed and would inherently conform to the a curvature of a canted passageway of a implantable medical device as well known in the art, in order for the helical fixation to reach the desired tissue site; therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Min et al. to include a preformed helical fixation element that has the ability to conform to the curvature of a canted passageway in order to enhance the ability of the fixation element in reaching the desired tissue site.

In regards to claims 12-18, these claim are rejected for similar reasons as set forth in the previous Office Action of February 13, 2006.

3. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Min et al. (U.S. Patent No. 6,937,897) in view of Grandjean (U.S. Patent No. 5,716,391) as

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applied to claims 1-8 and 12-18 above, and further in view of Altman et al. (U.S. Patent No. 6,416,510).

In regards to claim 9, although Grandjean teaches that helical fixation element (41) can comprise various materials (see for example col. 4 lines 29-35), it does not specifically teach of the use of a fixation element comprising a platinum-iridium alloy. However, Examiner maintains the position that it is well known in the art that fixation elements can comprise a platinum-iridium alloy, as taught by Altman et al. (see for example col. 10 lines 4-7). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Grandjean to include fixation element that comprises a platinum-iridium alloy, to ensure an effective fixation at a desired tissue site, as taught by Altman et al.

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Min et al. (U.S. Patent No. 6,937,897) in view of Grandjean (U.S. Patent No. 5,716,391) as applied to claims 1-8 and 12-18 above, and further in view of Keogh et al. (U.S. 2002/0138109).

In regards to claim 10, although Grandjean teaches that helical fixation element (41) can comprise various materials (see for example col. 4 lines 29-35), it does not specifically teach of the use of a fixation element comprising a super-elastic material. However, Examiner maintains the position that it is well known in the art that fixation elements/tissue engaging elements can comprise a super elastic material, as taught by Keogh et al. (see for example paragraphs 108, 118, 120). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify

the system as taught by Grandjean to include a fixation element that comprises a super-elastic element, to ensure an effective fixation at a desired tissue site, as taught by Keogh et al. (see for example paragraph 120).

5. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Min et al. (U.S. Patent No. 6,937,897) in view of Grandjean (U.S. Patent No. 5,716,391) as applied to claims 1-8 and 12-18 above, and further in view of Peterfeso et al. (U.S. Patent No. 6,298,272).

In regards to claim 11, although Grandjean teaches that helical fixation element (41) can comprise various materials (see for example col. 4 lines 29-35), it does not specifically teach of the use of a fixation element comprising a synthetic resin.

However, Examiner maintains the position that it is well known in the art that fixation elements can comprise a synthetic resin, as taught by Peterfeso et al. (see for example col. 18 lines 47-54). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Grandjean to include a fixation element that comprises a synthetic resin, as taught by Peterfeso et al. (see for example col. 4 lines 29-35).

6. Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Min et al. (U.S. Patent No. 6,937,897) as applied to claims 1-18 above, and further in view of Altman et al. (U.S. Patent No. 6,416,510).

In regards to claim 19, Min et al. does not specifically teach of the use of a radiopaque marker; however, Altman et al. teaches that the use of radiopaque markers (130) are well known in the art for determining for the position of implantable lead.

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Thus, it would have been obvious to one having ordinary skill in the art to modify the system as taught by Min et al. to include a radiopaque marker to facilitate the orientation of the lead, as taught by Altman et al.

In regards to claims 20-21, Examiner takes the position that although the Altman et al. reference does not specifically state the limitations of claims 20 and 21, Examiner takes the position that the system as taught by Altman et al. is inherently capable of providing these limitations. Or in the alternative, Examiner takes the position the limitation of claims 20 and 21, are well known in the art, and thus it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Min et al. to include such limitations in order to determine the orientation of the lead.

In regards to claim 22, Min et al. does not specifically teach of a fluid delivery lumen and the helical fixation member including a fluid infusion lumen; however, the Altman et al. reference teaches that it is well known in the art for medical leads/catheters (see for example Figure 1c) to comprise a fluid delivery lumens (see for example col. 10 lines 40-42), a helical fixation member (114) that includes fluid infusion lumen in communication with the fluid delivery lumen in order that a desired fluid may be infused out from the opening of the distal tip (see for example reference #132, col. 11 lines 2-19)

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. McVenes et al. (U.S. Patent No. 5,964,795), Rosenman et al. (U.S. Patent No. 6,478,776), Stewart et al. (U.S. 2001/0007070).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lenwood Faulcon, Jr. whose telephone number is 571-272-6090. The examiner can normally be reached on Monday-Thursday from 9 to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes, can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lenwood Faulcon, Jr.


George Manuel

Primary Examiner